CHAPTER 194
SCOPE OF PRACTICE REVIEW COMMITTEES

641—194.1(77GA,HF710) Purpose. The purpose of the scope of practice review process is to provide an objective method by which proposed changes in the regulation of health professions are evaluated. These changes include practitioners seeking to become newly regulated health professionals or to establish or substantially modify their own regulatory boards, health professionals seeking to expand or narrow the scope of practice of a health profession, and unresolved administrative rule-making disputes between boards. Review committees shall conduct impartial, analytical assessments using established objective criteria to develop recommendations to ensure and protect the public's health, safety and welfare.

641—194.2(77GA,HF710) Definitions.

"Applicant" means a board, health professional group or organization, or group of health care practitioners interested in proposing the regulation of any health professional group not currently regulated or the modification of the scope of practice of a regulated health profession.

"Board" means any board, commission, agency, division, or other unit of state government which regulates one or more health professions.

"Credential" means a license, certification, registration or other approval issued by the state to practitioners of a health profession.

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Economic harm or danger" means the existence of or significant potential for denied public access to high quality health care at a reasonable cost, needless health expense to the public, or serious economic consequences to the public.

"Health profession" means any regulated health profession identified in Iowa Code chapter 147, any other state-regulated health profession, or any health professional group not currently regulated whose principal functions, customarily performed for remuneration, are to render services directly or indirectly to individuals for the purpose of:

1. Preventing physical, mental, or emotional illness or injury;
2. Facilitating recovery from illness or injury; or
3. Providing rehabilitative or continuing care following an illness or injury.

"Physical or emotional harm or danger" means the existence of or significant potential for death, disability, or serious injury or impairment.

641—194.3(77GA,HF710) Letter of intent. An applicant shall submit a letter of intent to file an application to the director. The letter of intent shall identify the applicant and any group or groups the applicant represents, the proposed regulation or modification in scope of practice sought, and any other appropriate information to assist the director in determining whether the application is eligible for review, the prioritization of the request, and the allocation of department and committee resources. In determining the eligibility for review, the director shall confirm that the applicant and the applicant's request adhere to the intent and purpose of the scope of practice review process, determine whether there have been good-faith efforts by affected parties to resolve the scope of practice conflict or dispute, and consider the extent to which previous reviews have already been conducted and if all reasonable alternatives to review have been exhausted. The director shall notify the applicant within 15 days of the receipt of the letter of intent regarding the applicant's eligibility for review and the ability of the department to accommodate the applicant's request. The director shall consult with members of the general assembly, the administrative rules review committee, and boards in prioritizing eligible requests for review. For the purposes of judicial review, the decision of the director is the final agency action.

641—194.4(77GA,HF710) Application; contents. Upon notification of eligibility and capacity of the department to receive the applicant's request for review, an applicant shall submit a complete application on forms prescribed by the director. The application shall at a minimum include the following:

194.4(1) A narrative of the existing problem and why regulation or modification of the existing scope of practice of a health profession is necessary. This narrative shall include a complete and quantifiable description of the present condition that creates a situation of potential harm or danger to the public.

194.4(2) A detailed explanation of the specific request for the establishment of a regulated health profession or a modification of the existing scope of practice of a regulated health profession which is sought. This explanation shall include a discussion of whether the proposed change imposes any significant new harm or danger to the public, unnecessary health care costs, access or practice restrictions, and the extent to which the benefits of the proposal outweigh any new costs, restrictions, or harm or danger to the public.

194.4(3) A complete and quantifiable description of the anticipated public health, safety and welfare benefits which will be derived from the requested change.

194.4(4) An analysis of the alternative options available to achieve the desired outcome and a justification for the proposed method. This analysis shall include an explanation of why the public cannot be effectively protected by other more cost-effective means.

194.4(5) Identification of the applicant proposing the regulation, including a list of associations, organizations, and other groups the applicant represents and the number of members in each.

194.4(6) Identification of any individuals, professions, or other organizations most affected by or potentially opposed to the applicant's proposed changes.

641—194.5(77GA,HF710) Directed review. Any standing or interim committee of the Iowa general assembly may request a review to evaluate proposed legislation or administrative rules establishing a regulated health profession, modifying the scope of practice of an existing profession, or resolving disputes between health profession boards. The director, after conferring with members of the general assembly and the administrative rules review committee, may initiate a review to consider ongoing and unresolved disputes between health profession boards. Before initiating such a directed review, the director shall determine that no appropriate existing letter of intent or application exists. In addition to its normal duties and responsibilities, the review committee in a legislature- or director-initiated review shall also conduct an initial investigation to receive public input and comments in order to refine the issues that are the subject of the directed review, taking into account the information requested in rule 194.4(77GA,HF710).

641—194.6(77GA,HF710) Review committee; creation, membership. The director, in consultation with the state board of health, shall appoint the members of each review committee established. The director may consider nominations and recommendations from the applicant, affected health profession organizations, and other interested parties. A separate review committee will be established to evaluate every application accepted for review and each request for a directed review and shall, upon the completion of its duties, dissolve. Each review committee shall be comprised of five members, with one member representing the profession requesting the review, one member of a health profession most directly impacted by or opposed to the proposed change, one impartial health professional who is not directly or indirectly affected by the proposed change, and two impartial members of the general public. The director shall make all reasonable efforts to ensure that the total composition of the committee is fair, impartial and equitable. The director may also designate ex officio nonvoting members to the review committee if warranted. Situations which may warrant the designation of ex officio members include a scope of practice issue which directly affects any health profession not already represented in the committee composition.

Upon the appointment of a scope of practice review committee, the director shall provide for a public notice of the creation of the scope of practice review committee to be published in the Iowa Administrative Bulletin.

Both the applicant and the entity identified by the director as best representing the health profession most directly impacted by or opposed to the proposed change are entitled to and may reject one appointee to the review committee. The rejection must be received by the director in writing within ten days of the published notice. If a bona fide rejection is received, the director shall appoint the replacement member using the same criteria required in the selection of the rejected member and publish the revised scope of practice review committee membership in the Iowa Administrative Bulletin.

The committee shall elect from among its impartial members a chairperson. Three members shall constitute a quorum and the affirmative vote of three members shall be necessary for any action taken by the committee.

In the event of vacancies prior to the completion of the committee's duties, the director shall make the determination whether to fill the vacancy, using the same criteria required in the selection of the original member, or to dissolve the review committee. A vacancy shall be declared by the director upon the death, resignation, or failure to serve of any committee member.

The members of the committee shall be eligible for reimbursement of actual and necessary expenses for the performance of their official duties.

641—194.7(77GA, HF710) Committee duties. The review committee shall meet as soon as is reasonably possible upon its appointment and thereafter as necessary and appropriate to perform the following duties:

194.7(1) Review the application and information concerning the issues before the committee.

194.7(2) Provide a public forum and conduct public fact-finding hearings regarding the application and proposal in accordance with Iowa Code chapter 22. Receive verbal and written testimony. The committee shall establish procedures that encourage the involvement and participation of interested parties in the scope of practice review process. The applicant shall have the burden of bringing forth sufficient evidence by which the committee can base its findings and recommendations.

194.7(3) Conduct additional literature reviews and scrutinize existing research findings as appropriate based on the issues under consideration.

194.7(4) Analyze the application, testimony and relevant research materials in accordance with the applicable review criteria established in rule 194.8(77GA,HF710).

194.7(5) Within nine months from its appointment, develop committee recommendations and submit a final report to the director, affected boards and the Iowa general assembly as appropriate. If the committee finds that all the applicable criteria are met, it may recommend the implementation of the applicant's original request or any variation thereof as determined appropriate and in the public's best interest. If the committee finds that the applicable criteria are not met, it shall recommend against the applicant's request. In such a case, the committee shall provide in writing to the applicant with specificity an explanation of the reasons for the denial based on the criteria, standards and guidelines in rule 194.8(77GA,HF710).

194.7(6) In a case involving the establishment of new health care procedures for a health profession, the committee may recommend a controlled experimental trial which shall include but not be limited to an evaluation of patient outcomes.

194.7(7) If the committee recommends the creation of new regulations for a health profession not previously regulated, it shall identify the least restrictive method of regulation to be implemented which will achieve the desired public good.

194.7(8) Provide additional guidance to the director, department, boards and the Iowa general assembly on implementing the committee recommendations.

The director shall provide professional and clerical services to assist the committee in the fulfillment of its duties. Upon the completion of its duties, the review committee shall dissolve.

641—194.8(77GA,HF710) Criteria, standards and guidelines. The following criteria, standards and guidelines are established to assist review committees in evaluating applications. Not all guidelines will apply to every application. Each review committee should examine the extent to which any guideline is relevant to the application and apply those which are relevant in its deliberations and recommendations. The director reserves the right to request that a review committee reconsider whether a guideline is relevant to an application.

194.8(1) *Potential harm or danger of present condition.*

a. Criterion 1. The present condition creates a situation of actual or potential harm or danger to the public.

b. Standard. In order to find that this criterion is met, the review committee must determine that the public is currently suffering, or at serious risk of suffering, harm or danger, that this harm or danger is directly attributable to the present scope of practice, limitations on scope of practice, or the absence of the proposed regulation of the health profession, and that the harm or danger is of sufficient magnitude to warrant intervention.

c. Guidelines.

(1) Physical or emotional harm or danger, or economic harm or danger to the public can be demonstrated.

(2) Harm or danger to the public must be directly and primarily attributable to the absence of the proposed regulation of the health profession.

(3) Harm or danger to the public must be of sufficient extent and severity to warrant government intervention by statute, rules or further regulation of the health profession.

(4) Documentation that the harm or danger to the public is directly and primarily attributable to the absence of the proposed regulation of the health profession may include but is not limited to:

1. Testimony of clients or consumers;
2. Testimony of acknowledged experts or leaders in the appropriate fields;
3. Research and statistical studies from generally accepted sources;
4. Records of judicial rulings and financial settlements as appropriate; and
5. Evidence of disciplinary actions taken against credentialed individuals or actions against non-credentialed individuals by the appropriate boards.

194.8(2) *Significant new harm or danger of proposed change.*

a. Criterion 2. The proposed change does not impose any significant new harm or danger to the public.

b. Standard. In order to find that this criterion is met, the review committee must determine that the implementation of the proposed regulations would not impose any unnecessary health care costs, access or practice restrictions, or significant new harm or danger to the health, safety, or welfare of the public. Any costs, restrictions, or harm created must be outweighed by the benefits of the proposed change.

c. Guidelines.

(1) Demonstration of barriers to service may be accomplished by identifying any factors that impede the ability of the public to have access to high quality health care services at a reasonable cost. These factors may include but are not limited to:

1. Increased cost for the same service;
2. Decrease in the number of qualified practitioners;
3. Concentration of providers in a few locations;
4. Lowering the quality of services;
5. Eliminating or denying third-party reimbursement for services; or
6. Fragmentation of the health care delivery system.

(2) If a scope of practice is established or modified, the scope of practice must be coordinated with those of related professions to minimize fragmentation of the health care system.

(3) The modification in or the regulation of a new health profession must not lead to unnecessary limitations on the utilization of appropriate personnel by employers or the underutilization of qualified personnel.

(4) Regulation of a health profession must not result in an unnecessary reduction in competition.

(5) The expected costs associated with the application, including the costs associated with regulation of the health profession and the cost to the health care industry and general public of implementing the proposed change, must be ascertained. Source of funding sufficient to support the cost of regulation, including health profession credentialing fees and general fund support, should be identified.

194.8(3) *Public health, safety and welfare benefits.*

a. Criterion 3. The public health, safety and welfare are reasonably expected to benefit from the requested change.

b. Standard. In order to find that this criterion is met, the review committee must determine that the ability of the public to achieve ready access to high quality health care services at reasonable costs will be significantly enhanced by implementation of the proposed change. Review committees must focus on the determination of the demonstrated need for and public benefit from the proposed regulation. Demand for regulation by the profession or the consumer public shall alone not be sufficient to demonstrate need.

c. Guidelines.

(1) The need for the regulation of a health profession must be evident to persons outside the affected profession.

(2) The extent to which the public will be reasonably assured that credentialed health professionals are competent must be demonstrated. Competency may be determined by considering whether:

1. The proposed regulatory board has the appropriate authority and capacity to credential, investigate, and suspend or revoke credentials;
2. Adequate provisions have been made to ensure continued and uninterrupted access to health services;
3. Adequate provisions have been made to address individuals and health professionals authorized to provide the health services prior to the implementation of the request;
4. Appropriate training and educational standards, qualifications, and supervision are established; and
5. Mechanisms to ensure the continued competence of credentialed health professionals are established.

(3) If the proposed regulated profession is generally supervised by members of other credentialed or regulated professions, or if the affected profession practices under institutional or similar regulation, it must be demonstrated that the existing supervision or regulation is not sufficient to protect the public.

(4) The extent by which the enactment of the proposed change would improve the ability of the public to have access to high quality health care at a reasonable cost, reduce or eliminate unnecessary cost to the public, or otherwise contribute economic benefit to the public.

(5) Documentation which demonstrates a reasonable expectation that implementation of the proposed change will result in the asserted benefits to the public. This documentation may include:

1. Testimony of patients or clients;
2. Testimony of regulatory authorities and persons who have benefited from similar regulatory changes in other states;
3. Testimony of acknowledged experts or leaders in the appropriate fields;
4. Research and statistical studies; and
5. Affirmation by knowledgeable persons other than individuals with a direct interest in the proposed change.

194.8(4) *Cost-effective means.*

a. Criterion 4. The public cannot be effectively protected by other more cost-effective means.

b. Standard. In order to find that this criterion is met, the review committee must determine that the proposed regulation is an effective remedy to the problems identified, and that less costly means of dealing with these problems do not exist. The review committee must conclude that maintaining the status quo is costlier to the public than the proposed change.

c. Guidelines.

(1) The evidence must demonstrate that implementation of the proposed change will clearly, specifically, and directly solve or alleviate the potential harm or danger to the public as identified in the application.

(2) Any and all evident alternatives to the proposal must be evaluated to determine if they might be a more efficient method of ensuring the public health, safety and welfare. This evaluation shall include a review of recognized systems of private credentialing, professional standards of conduct and codes of ethics.

(3) Methods which demonstrate cost-effectiveness may include, but are not limited to:

1. The request for regulation is commensurate with the extent of potential harm or danger;
2. There is no other reasonable means by which to protect the public; or
3. Effective supervision of practitioners by members of an existing health profession is inappropriate or fails to provide adequate safeguards to protect the public.

641—194.9(77GA,HF710) Pilot project, evaluation; report to the general assembly. The scope of practice review process and committees are initiated as a pilot project commencing on July 1, 1997, and ending June 30, 2000.

The director shall submit a final report to the general assembly by January 1, 2000, detailing an evaluation of the degree of success realized by the pilot project in implementing scope of practice review committees; a description and explanation of all applications received and issues reviewed; a synopsis of the impact and contributions review committee recommendations had on public health care policy development; and suggestions regarding the continuation of and modifications in the scope of practice review process.

These rules are intended to implement 1997 Iowa Acts, House File 710, section 6.

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